

# STATE OF MARYLAND

## Maryland Department of Health and Mental Hygiene

201 W. Preston Street • Baltimore, Maryland 21201 Larry Hogan, Governor – Boyd Rutherford, Lt. Governor – Van Mitchell, Secretary

Audrey C. Clark, MPA, Chief, Division of Drug Control, Public Health Services

**Division of Drug Control** 4201 Patterson Avenue • Baltimore, Maryland 21215 Main Office: 410-764-2890 • Fax: 410-358-1793

## **Controlled Dangerous Substances (CDS) Researcher Questionnaire**

Applicant Name			
Facility Name			
Address			
Telephone			
E-mail Address			
Maryland CDS Registration Number			Exp. Date
DEA Registration Number Sat Sun			Exp. Date
Hours of Operation M-F	Sat	Sun	<u> </u>
<ol><li>Brief description of the researd will be used.</li></ol>	ch that will be	conducted and ho	w controlled dangerous substances (CDS)
3. List the approximate quantitie	s of each CDS u	ised per vear. Inc	lude strength or concentration of the CDS
and container size.	s or each CDS u	iseu pei year. IIIC	tude strength or concentration of the CDS

4. Who are the individuals with access to the CDS. Include job title and/or professional title and/or educational degree for each person. Individuals with access include all persons with access to the CDS storage area and all persons that handle the CDS.
5. What is the exact location in your facility where CDS will be stored? <i>Include the location/name of the</i>
building and room number of the storage area.
6. Provide the name, address, phone number, DEA registration number, Maryland CDS registration number and (if applicable) the Maryland Board of Pharmacy distributor or pharmacy permit for ALL suppliers of CDS. Suppliers of prescription CDS products must have a Board of Pharmacy distribution permit or pharmacy permit. Suppliers of CDS bulk powders and chemicals do not require a Board permit. You may not purchase or receive CDS from a supplier that does not have an active Maryland CDS registration.
7. Provide the name, address, phone number and DEA number of the reverse distributor used for disposal of outdated/unwanted CDS. (COMAR 10.19.03.10D) Any alternate disposal procedure must be approved in writing from your local DEA office. Written permission should be kept on file at the site.
8. What procedures are used to ensure secure delivery and receipt of CDS?
<b>9. How will CDS be stored?</b> CDS must be kept either in a lockable safe or under a double lock system (a locked drawer or cabinet within a room with a lockable door). Storage area and/or safe should be kept locked when not in use and ONLY accessible to individuals approved by the registrant.

### PLEASE READ AND INITIAL THE FOLLOWING REQUIREMENTS AND RECOMMENDATIONS

<ul> <li>An initial inventory must be taken of all CDS items present prior to the opening of the business. If no CDS products are present, state "No CDS products at opening of business". [21 CFR 1304.11] (initial)</li> </ul>			
<ul> <li>You are required to take a biennial CDS inventory, which is a physical inventory of all controlled substances on hand that is taken at least every two years. The biennial inventory may be taken on any date, which is within two years of the previous biennial or initial inventory. [21 CFR 1304.11] (initial)</li> </ul>			
• When taking a CDS biennial inventory, schedule II items should be listed separately from the schedule III-V items. An exact count must be made of all schedule II items. Schedule III-V items may be estimate, but if fractions or decimals are used, then the container size must also be included. An exact count must be made if CIII-V products are in opened containers of greater than 1,000 tablet or capsules. All CDS, including expired and unwanted items, must be included in the inventory. The entire inventory should be taken on the same day with the same reference point (either before opening of business or after close of business). The date taken and reference point should be present on the inventory. [21 CFR 1304.11] (initial)			
<ul> <li>Invoices for schedule III-V must be physically dated upon receipt. It is recommended that these invoices by filed separately. [21 CFR 1304.21] (initial)</li> </ul>			
<ul> <li>DEA 222 forms, used to order schedule I-II products, must be signed by the person who signed the most recent application for the establishment's DEA registration. A power-of-attorney may be executed by the person authorized to sign the DEA 222 form, to allow others to sign the DEA 222 form. The power-of-attorney must be kept on file at the registered site. [21 CFR 1305.05] (initial)</li> </ul>			
<ul> <li>When schedule I-II orders are received, the quantity and date received must be recorded for each line item on DEA Form 222. [21 CFR 1305.13(e)] (initial)</li> </ul>			
<ul> <li>Executed DEA 222 Forms must be maintained separately from other records and kept readily available for 2 years. [21 CFR 1305.17] (initial)</li> </ul>			
• The theft or significant loss of CDS must be reported immediately upon discovery, within one business day, in writing, to the local DEA office and the Division of Drug Control. A DEA Form 106 must be completed for any theft or significant unresolved loss of CDS, with the original sent to DEA and a copy sent to DDC. The DEA 106 Form may be filled out and sent electronically to the DEA, but a copy must be printed and sent to DDC. [COMAR 10.19.03.12B(4)] ()			
NOTE: Please ensure all questions have been answered completely. Incomplete answers or missing information will result in a delay in the processing of your CDS application.			
Signature of Applicant Date			
Print Name of Applicant			

Division of Drug Control • 4201 Patterson Avenue • Baltimore, Maryland 21215-2222 410-764-2890 • Fax 410-358-1793 • TTY for Disabled - Maryland Relay Service 1-800-735-2258 Toll Free 1-877-4MD-DHMH • Web Site: <a href="http://dhmh.maryland.gov/drugcontrol">http://dhmh.maryland.gov/drugcontrol</a>

Rev 04/05/2016